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REMARKS

Following entry of the above amendments, claims 1-5, 8-13, and 15 are pending. Claims 6, 7, 14, and 16-17 are cancelled, and claims 18-19 have been withdrawn by the examiner as being drawn to a non-elected invention. Claims 1, 8, 11-13, and 15 have been amended to correct punctuation, place the claims in a form more appropriate for US practice, and to focus on particular embodiments of the invention. Support for the amendments can be found in the specification as originally filed. See, for example, the claims as originally filed, and pages 62-91 and the examples therein.

Restriction Under 35 USC §121 & §372

The Examiner states that the instant application contains inventions or group of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1, and requires Applicants to elect a single invention, for purposes of restriction, from the following:

Group I, claims 1-15, drawn to the compounds of formula I; and

Group II, claims 18-19, drawn to the method of treating various diseases with the compounds of formula I.

Confirming an earlier telephonic election, Applicants provisionally elect Group I, with traverse.

The Examiner states that restriction due to lack of unity is necessary because Groups I and II lack the same or corresponding special technical feature under PCT Rule 13.2, and do so for two reasons. The first reason given by the Examiner is that although Groups I and II are linked by the technical feature of the compound of formula I, the compound of formula I does not make a contribution over the prior art as evidenced by Kamiya et al., thus, the compound of formula I does not link the product and method claims into a single general inventive concept. The second reason given by the Examiner is that the alternative members of the Markush group of compounds in Groups I and II do not have common cores.

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In response to the Examiner's first reason, Applicants refer the Examiner to MPEP §1850(III)(B) "Markush Practice," last paragraph. MPEP §1850(III)(B) states, in pertinent part:

"[w]hen dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised."

The MPEP references the examples contained in Chapter 10 of the International Search and Preliminary Examination (ISPE) Guidelines. Section 10.02 of the ISPE states:

"[w]hether or not and particular technical feature makes a 'contribution' over the prior art, and therefore constitutes a 'special technical feature,' is considered with respect to novelty and inventive step."

Further, section 10.07 states, in pertinent part, "no problem arises in the case of a genus/species situation where the genus claim avoids the prior art and satisfies the requirement of unity of invention."

The Examiner does not state in her first reason that the genus does not satisfy the requirement of unity of invention, thus the issue is that the genus does not avoid the prior art. Applicants have amended claim 1. The genus of claim 1, as amended, avoids the prior art with respect to novelty and inventive step. Thus, formula I, as amended, avoids the prior art and satisfies the requirement of unity of invention. Therefore, Applicants respectfully request withdrawal of the unity of invention restriction as based on the Examiner's first reason of the compound of formula I not making a contribution over the prior art.

In response to the Examiner's second reason, it is unclear how the Examiner's assertion that compounds of formula I of Groups I and II do not have common cores supports a restriction among Groups I and II. It is not clear whether the Examiner is saying that the compounds of formula I lack common cores, and therefore cannot be the special technical feature required

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to unify Groups I and II, or if the Examiner is actually requiring a further restriction among compounds of formula I, stating that the compounds themselves lack unity because they do not have common cores. In the case of the latter, the restriction seems to be not among Groups I and II, but rather among the compounds of Group I themselves.

Following the Examiner's statement about the compounds lacking common cores, the Examiner cites MPEP section 1850, Section III, part B, relating to Markush Practice. Based on this citation, and the Examiner's other statements in the Office Action, Applicants believe that the Examiner is trying to require a restriction among Groups I and II for lack of a qualifying special technical feature, and the special technical feature, as the Examiner notes, is the genus of compounds of formula I. However, in order for the compounds of formula I to qualify as the special technical feature to unify the inventions of Groups I and II, the compounds themselves must meet the requirements for unity of invention as described in MPEP §1850(III)(B) "Markush Practice." Therefore, in an attempt to further prosecution, Applicants provide the following response directed to the restriction requirement among Groups I and II.

In order for the compounds of formula I to provide the unifying special technical feature for the inventions of Groups I and II, the individual species that comprise the genus represented by formula I must meet the requirements for unity of invention. For a national stage application filed under 35 U.S.C. §371, PCT Rules 13.1 and 13.2 shall apply when determining unity of invention among species. As stated in MPEP §1850(III)(B) "Markush Practice," in pertinent part, Rule 13.2 shall be considered to be met when the [chemical] alternatives are of a similar nature. [C]hemical compounds shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives.

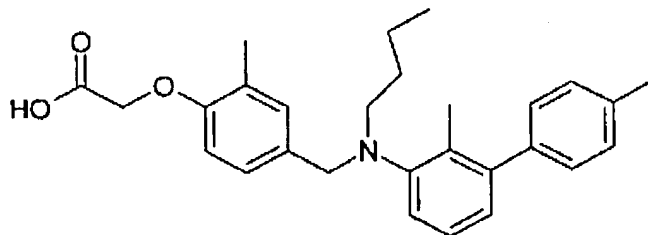
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The Examiner does not dispute that the compounds of the present invention all have a common property. Therefore, the issue is whether the compounds share a significant structural element. MPEP §1850(III)(B) provides, in pertinent part, that a "significant structural element is shared by all of the alternatives" when compounds share a common chemical structure which occupies a large portion of their structures, and the common structure is essential to the common property or activity. Furthermore, the structural element may be a single component or a combination of individual components linked together. The claimed compounds of the present invention possess a common chemical structure that occupies a large portion of their structures, and the common structural element is a combination of individual components linked together. As shown by formula I in claim 1, as amended, the components of formula I linked together provide the requisite common structural element (for example, from right to left, an optionally substituted six membered cyclyl group is linked to a nitrogen, which is linked to the atom "X¹," which is further linked to a substituted phenyl, which is further linked to the atom "X" (para to the point of attachment of the phenyl to the atom "X¹"), which is further linked to an optionally substituted methylene linker, which is further linked to the group -C(O)OH). Since the compounds of formula I possess a common structural element that occupies a large portion of their structures, as defined in §1850(III)(B) "Markush Practice" (B)(1), the compounds meet the requirement for unity of invention of species under PCT Rule 13.2. Since the compounds of formula I do not lack unity, they qualify as the special technical feature necessary to unify the inventions of Groups I and II. Therefore, Applicants respectfully request withdrawal of the restriction requirement among Groups I and II, with respect to the Examiner's second reason for lack of unity among the inventions of Groups I and II.

The Examiner states that the Applicants are required to elect a single disclosed species to which claims shall be restricted if no generic claim is finally held to be allowable. In order to further prosecution, and to confirm a previous telephonic election, Applicants provisionally elect, with traverse, the species of example 25 on page 75, also known as (4-[[butyl(2,4'-dimethyl-

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1,1'-biphenyl-3-yl)amino]methyl)-2-methylphenoxy)acetic acid, and having the structure



Additionally, Applicants identify claims 1-5, 8-13, and 15 as the claims readable on the elected species.

The Examiner has requested an election of species. However, the Examiner provides no basis for the election requirement. As stated, in pertinent part, in MPEP §1893.03(d), "[e]xaminers are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 USC §371." The instant application is a national stage application filed under 35 U.S.C. §371. Therefore, a request for an election of species for the instant application must be either (1) a restriction requirement among species for lack of unity under PCT Rules 13.1 and 13.2, or (2) a provisional election for purposes of aiding examination, where such election may flow from 37 C.F.R. 1.141 and 1.146.

If the Examiner is requesting an election of species for purposes of restriction, such restriction among species must be due to a lack of unity under PCT Rules 13.1 and 13.2, and not U.S. restriction practice under MPEP §800 *et seq.* Applicants have addressed the issue of unity among species in the instant application in the above paragraphs. See, for example, pages 11 and 12 of this response. For these reasons, the individual species of the instant invention do not lack unity, thus an election of species for purposes of restriction is improper. Therefore, Applicants respectfully request withdrawal of the election requirement for purposes of restriction.

If the Examiner is requesting a provisional election of species for purposes of aiding examination, such election request may flow from 37 CFR 1.141 and 1.146. Where the election is a provisional election for aiding

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examination, 37 CFR 1.146 provides that the Examiner may request an election of species, but is not required to, so long as the application meets the remaining requirements under 37 C.F.R. 1.141. Applicant believes that the instant application contains an allowable generic claim to all of the claimed species, thus it meets all of the provisions of 37 C.F.R. 1.141. However, since the Examiner may request such an election, an election requirement for purposes of aiding examination may be proper in the instant application. Therefore, Applicants have made the provisional election of the species disclosed in example 25 on page 75 of the specification as originally filed. Applicants respectfully request that the application be examined in light of the provisional election, and all requirements for a restriction among species be withdrawn.

Rejection Under 35 USC §112, Second Paragraph

The Examiner states that claim 12 is rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states the phrase beginning with "wherein phenyl" is unclear. Applicants have amended claim 12 to more particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Therefore, Applicants respectfully request withdrawal of the rejection.

Rejections Under 35 USC §102(b)

Claims 1, 2, 3, 5, 6, 11, 12, and 15 are rejected under 35 USC §102(b) as being anticipated by Kamiya et al. (Reference A), HCAplus 68:49243 (Reference U), and HCAplus 86:55153 (Reference V). Applicants amend claims 1, 11, 12, and 15, to focus on particular embodiments of the invention. Applicants cancel claim 6. Claims 2, 3, and 5 depend from claim 1 as amended. The amendments overcome the Examiner's rejections, and respectfully request withdrawal of the rejections.

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Rejection Under 35 USC §103(a) – Kamiya et al.

The Examiner states that claims 1, 2, 3, 5, 6, 11, 12, and 15 are rejected under 35 USC §103(a) as being unpatentable over Kamiya et al. since Kamiya teaches a small group of compounds within a genus that overlap in subject matter with the Applicant's genus. Applicants amend claims 1, 11, 12, and 15, to focus on particular embodiments of the invention. Applicants cancel claim 6. Claims 2, 3, and 5 depend from claim 1 as amended. As amended, the genus of the instant application no longer overlaps in subject matter with the teachings of Kamiya. Therefore, the amendments overcome the Examiner's rejection. Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 USC §103(a) – HCAplus 86:55153.

The Examiner states that claims 1, 2, 3, 5, 6, 11, 12, and 15 are rejected under 35 USC §103(a) as being unpatentable over HCAplus 86:55153 since 86:55153 teaches a small group of compounds within a genus that overlap in subject matter with the Applicant's genus. Applicants respectfully note the following:

- (1) HCAplus record 86:55153 is the record for Kamiya et al.; and
- (2) The example given by the Examiner of "the compound of formula I wherein R is alkyl, R2 and R3 is H, alkyl, R4 is CO2H, Z is alkylene, and R1 is alkyl, aryl, aralkyl" does not correspond to the genus defined in either the instant application or the cited reference. For example, neither the instant genus nor the Kamiya genus has variables R or Z.

In response to the Examiners rejection based on (1) namely the HCAplus record 86:55153, Applicants reiterate the arguments in the prior paragraph of the response to the rejection based on Kamiya et al. since the references are cumulative over each other. For such reasons as stated in the above arguments, Applicants respectfully request withdrawal of the rejection.

In response to the Examiner's rejection based on the example as shown in (2) above, Applicants are unable to respond since the definitions given by the Examiner do not correspond to either the instant genus or the

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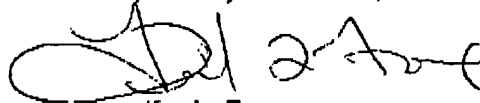
genus of the cited reference. Therefore, Applicants respectfully request either withdrawal of the rejection, or clarification of the rejection in a future office action.

Applicant has attempted to fully respond to what Applicant believes to be the restriction requirements being made by the Examiner, as well as the remaining rejections of the Office Action. However, Applicant believes that no restriction is required in the instant application, among Groups I and II, or among species, for the reasons stated above. Additionally, Applicants submit that following entry of the above amendments and consideration of the above arguments, Applicants have overcome the Examiner's rejections. Applicants believe the present claims are in condition for allowance and such action is respectfully requested.

Applicant believes that no fees are due in connection with the filing of this paper other than those specifically authorized herewith. However, should any other fees be deemed necessary to effect the timely filing of this paper, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 07-1392.

If the Examiner has any outstanding issues with the pending claims, the Examiner is encouraged to telephone the undersigned at (919)483-6334 for expeditious handling.

Respectfully submitted,



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